Chapter 2
Ecological Risk Assessment Scoping Considerations

2.1 Introduction

This chapter introduces the conceptual and technical objectives for scoping an ERA and the elements that should be included in an ERA. The methodology for conducting the ERA is presented in greater detail in the following chapters. Chapters 2 through 8 are intended as a guide for enabling a risk assessor and risk manager to critically scope and evaluate ERAs, as well as appraise their quality for supporting potential site remedial responses at his or her site. These chapters present important components of the risk assessment, highlighting where planning and professional judgment are needed. They are not intended to present step-by-step instructions. Adequate guidance for preparing an ERA is provided in other resources as referenced throughout this manual.

The ERA is an integral component of the PA/SI, RFA, RI/FS, RFI/CMS, and emergency response processes. It serves multiple roles regarding the need for action at a site:

- The ERA provides an evaluation of the potential ecological risks under baseline (i.e., no action) conditions.
- The ERA helps to determine the need for remedial action at the site.
- The ERA provides a basis for determining remediation goals for chemicals in site media.
- The ERA can be used as a basis for comparing different remedial alternatives.
- The ERA provides a means for assessing potential ecological risks and for allowing comparison of potential ecological risks between sites.

The ERA is one component of overall site investigation and remedial activities. It should be developed with a recognition of how it is supported by preceding and concurrent components of site activities, such as sampling and analysis and the human health risk assessment effort, and how it supports and shapes the following components, such as remedial design. Although the ERA is performed to achieve several specific objectives (describing current and future ecological risks), it needs to be coordinated with other site activities (e.g., human health risk assessment) and needs to be responsive to other general site concerns (e.g., restoration, mitigation, litigation) and the resources (cost and schedule to be met) available.

Risk assessments have different applications in different regulatory programs.[1] The application of risk assessment is discussed in the following phases of site activity:

- PA/SI and RFA.
- RI and RFI.
- FS and CMS activities, including development of remediation levels and comparative risk assessments associated with selected remedial options followed by the evaluation of short-term risks associated with the implementation of the selected remedial option.
- RD/RA and CMI activities, including potential need to further evaluate short-term risks for the purpose of designing/implementing control measures.
- Assessment of residual risk after implementation of the selected remedial option.

Risk assessments developed for each of these activities will have slightly different scope or level-of-effort requirements. However, the technical basis for the risk assessment is essentially the same.

EPA's *Framework* (EPA 1992a) and *Risk Assessment Guidance for Superfund, Volume II (RAGS II),* (EPA 1989a) provide the general guiding principles and structure for the conduct of an ERA and the format of this manual. Forthcoming guidance from EPA Headquarters, Environmental Response Team (ERT), is expected to provide further details on an eight-step process for designing and conducting ERAs based on the *Framework* (M. Sprenger, EPA 1995c). Additionally, USAERDEC's (1994) *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* presents a similar framework

[1] Performance of an EBS under the BRAC program is not addressed in this guidance. However, the general concepts, particularly those for the Tier I ERA, are applicable to this program to meet the objectives of the Community Environmental Response and Facilitation Act (CERFA).

approach and a three-tier investigative process used to further enhance an understanding of the ERA requirements under CERCLA.

The framework for ERAs as presented in these references is conceptually similar to the approach used for human health, but is distinctive in its emphasis in three areas. First, the ERA can consider effects beyond those individuals of a single species and may examine a population, community, or ecosystem. Second, no single set of ecological values to be protected can generally be applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Finally, in addition to chemical-induced toxic stresses, ERAs may consider nonchemical-induced stresses (e.g., loss of habitat).

2.2 Scoping Considerations

The consistent standardized approach presented in these guidance documents was devised to ensure consistent treatment among sites. For scoping purposes, it should be noted that most ERAs are highly site-specific and often require unique investigative plans and actions. Numerous other resource materials, guidance documents, bulletins, memoranda, technical manuals, and books that address the general ERA approach and scoping of site-specific data needs are available from EPA, other regulatory agencies, and scientific sources. A number of these resources are referenced in Appendix B. A copy of the Framework (EPA 1992a) is provided in Appendix C. The following chapters provide the USACE risk manager with more detailed guidance information on the ERA process, along with "how to" and "where to find" knowledge for evaluating the scope, design, and conduct of a site-specific ERA.

2.2.1 Objectives of the Ecological Risk Assessment

The goat of the ERA is to provide the necessary information to assist risk managers in making informed decisions. The specific objectives of the ERA are: (1) to identify and characterize the current and potential future threats to the environment from a hazardous substance release; and (2) to establish remedial action objectives that will protect those ecological receptors at risk, if appropriate. The ERA provides important risk management input at various project phases, identifying ecological species or resources to be protected, as well as limitations and uncertainty.

The ERA should provide an objective, technical evaluation of the potential ecological impacts posed by a site., with the risk characterization clearly presented and separate from any risk management considerations. Although risk assessment and risk management are separate activities, the risk assessor and risk manager need to work together at various stages throughout the project to define decision data needs. In the ERA, the risk assessor needs to present scientific information in a clear, concise, and unbiased manner without considering how the scientific analysis might influence the regulatory or site-specific decision. The risk assessor is charged with:

- Generating a credible, objective, realistic, and scientifically balanced analysis.
- Presenting information on the problem, effects, exposure, and risk,
- Explaining confidence in each assessment by clearly delineating strengths, uncertainties, and assumptions, along with impacts of these factors (EPA 1995a).

The risk assessor does not make decisions on the acceptability of any risk level for protecting the environment or selecting procedures for reducing risk. The ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

2.2.2 Definition of Ecological Risk Assessment

According to EPA's *Framework* (EPA 1992a). an ERA is defined as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors. Stressor is defined by EPA as any physical, chemical, or biological entity that can induce an adverse ecological response. In the Superfund program, an ERA entails the qualitative and/or quantitative appraisal of the actual or potential impacts of a hazardous waste site on plants and animals other than humans or domesticated species. Substances designated as hazardous under CERCLA (see 40 CFR 302.4) are the stressors of concern. These definitions recognize that a risk does not exist unless: (1) the stressor has an inherent ability to cause adverse effects, and (2) it co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s).

No consensus definitions exist for many of the terms used in an ERA. Definitions herein are generally consistent with those used in the *Framework* (EPA 1992a) and *RAGS II* (EPA 1989a).

2.2.3 Planning for an ERA

Planning and problem identification are critical to the success of the ERA and its usefulness with respect to remediation planning. To ensure that the scope. of the ERA is sufficient for making risk management decisions, the risk assessor must always be mindful of the question, "Do the data and ERA approach support risk management decision-making?"

Planning for an ERA should be conducted concurrently with that for a human health assessment in that these two efforts often have similar data needs. ERA data needs are generally similar to those for human health risk assessments in the initial contamination characterization stages. Data needs for the ERA, however, eventually focus on developing remedial alternatives that are protective of ecosystem components, while the human health risk assessment focuses on developing remedial alternatives that are protective of a single species, humans.

Coordinated planning efforts for the ecological and human health risk assessment efforts, particularly where there is to be an expedited cleanup, should include consideration of the following:

- Overlaps in information needs with regard to human and ecological food chain issues.
- Benefits of the cleanup and the effectiveness of presumptive remedies.
- Ecological impacts from removal or remedial activities designed to protect human health.
- Identification of hot spots that may impact both human health and ecological receptors.
- Identification of the key assumptions and criteria common to the human health and eco-risk risk assessments that may drive cleanup decisions and focus the decision-making process.
- Early actions which may be taken at sites (i.e., OUs, CAMUs) that could quickly and at a relative lower cost reduce both ecological and human health risk.
- Identification of areas of greatest concern that may be addressed as discrete tasks in the ROD, thereby allowing priority to be given to those (removal/remedial) actions that achieve the greatest protection of the environment and human health for the capital (dollars) spent.
- Activities common to both the ecological and human health risk efforts that support DOD responsibilities as a Natural Resource Trustee or help coordinate between multiple Natural Resource Trustees where jurisdictions or responsibilities overlap.

ERAs employ a systematic planning format and process to ensure production of consistent and technically defensible ERAs. The ERA format and process, as described in the Framework, is designed to be flexible. Widely applicable regulatory protocols for formal site-specific ERAs are currently not available (in contrast to the approach used for human health). The flexible ERA process provides for coordination with the human health assessment in the chemical sampling program, determination of extent and degree of contamination, characterization of site risk. and the overall site management decision process.

In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, regulatory programs driving the HTRW project execution and the associated project decision statements (PDs),[2] the study elements for the relevant project phase, and the type of ERA needed based on the study elements. The concept of technical project planning is fully explained in the USACE's (1995b) Technical Project Planning Guidance for HTRW Data Quality Design, which emphasizes the need for the data users (e.g., the risk assessor) to identify minimum data requirements for the tasks to be performed.[3] The concept of "minimum requirements" for

[2] PDs represent specific planning objectives of HTRW site investigations and evaluations. Selected PDs become the principal focus of the data quality design efforts (USACE 1995b).

[3] The HTRW technical project planning is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options. Throughout the process, USACE HTRW personnel of various disciplines and responsibilities (some of whom may assume multiple responsibilities) work closely together to identify data needs, develop data collection strategy, and propose data collection options for the customer. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all phases of the project life cycle.

the ERA is important in that it identifies certain minimum requirements for data collection activities preceding the ERA to ensure that critical data gaps or factors are addressed. Examples of minimum requirements for a risk assessment are presented in Exhibit 1.

The approaches and contents of the anticipated ERA should be explained or discussed in the project planning stage in unambiguous terms. An iterative, tiered approach to the risk assessment, beginning with screening techniques, is used to determine if a more comprehensive assessment is necessary. The nature of the risk assessment depends on available information, the regulatory application of the risk information, and the resources available to perform the ERA. Informed use of reliable scientific information from many different sources is the central feature of the ERA process (EPA 1995a,d). The project planning process should produce an outline for a site-specific ERA that is credible, objective, realistic, and scientifically balanced. Since the ERA is conducted in an iterative, tiered approach, a decision diagram similar to that presented in Figures 2-l and 2-2[4] should be presented for discussion.

Throughout the planning discussions, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "'real world" situation. Biological sampling programs often entail scheduling constraints, e.g., surveys for endangered speties (e.g., an orchid) should be conducted in the appropriate season (e.g., June, not December). When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed. The risk assessor should also explain the minimum data quality considered to be acceptable, how nondetects will be treated, and how medium-specific data will be evaluated or compiled to derive or model the exposure point concentration in the risk assessment[5]

[4] Details presented on the tiered ERA process in these figures are elaborated upon in succeeding chapters. See Section 2.4 for an introduction to USACE's four-tiered EPA approach.

[5] For example, if the RI data are skewed, it may be necessary to address site risk by evaluating hot spots separately. The risk assessor may wish to indicate this in the Work Plan, in order to characterize hot spot areas without delaying the assessment of risks for the non-hot-spot areas.

The technical requirements of the ERA should be considered early in the HTRW process to ensure that appropriate information is gathered. It is important that the ecological risk assessor be involved in the early planning stages of field investigations, including ECSM develop ment, identification of site media, sampling plan design, data validation, compilation, and interpretation. This will help ensure that the best possible and most relevant data are available for use in the ERA. Coordination with an agency (EPA or DoD [USAEC]) BTAG/ETAG coordinator will also help ensure conduct of an effective and acceptable ERA.

The ERA should be developed, to some extent, with its end uses in mind. Early interaction with risk managers and remedial designers is needed to obtain information on the risk management options likely to be considered if remedial action is required. This is not to infer that the ERA should be tailored to specific remedial options, for that would compromise the objective nature of the assessment. However, if the risk manager or remedial designer needs to know certain factors (for example, how thick must the cap be to prevent onsite burrowing animals from being at risk), the risk assessor should provide the basis that will allow him or her to answer this question.

In the risk planning process and on Superfund sites in particular, it is also important for the risk assessor, risk managers, and decision-makers to coordinate with natural resource trustees (e.g., DoD, the State, NOAA[6] USFWS, USFS, and BLM) at the earliest possible stage. In this

[6] NOAA's Coastal Resource Coordination Branch (CRCB) works with EPA through all phases of the formal remedial process at Superfund waste sites. The CRC Branch acts for the Dept. of Commerce as trustee for natural resources such as anadromous and marine fish. Coastal Resource Coordinators (CRCs) and an advisory staff of environmental, marine, and fisheries biologists provide technical support and expertise to EPA, DoD, and other agencies during response and cleanup at coastal waste sites. The CRCs and supporting staff recommend appropriate environmental sampling, coordinate with other natural resource trustee agencies to build consensus on natural resource issues, and recommend appropriate cleanup levels. The CRCB works with EPA to gain cost-effective remedies that minimize residual resource injury without resorting to litigation. CRCs are in most EPA regions (not in Regions 7 and 8; coming soon to Region 5). See Appendix B for additional information on NOAA programs.

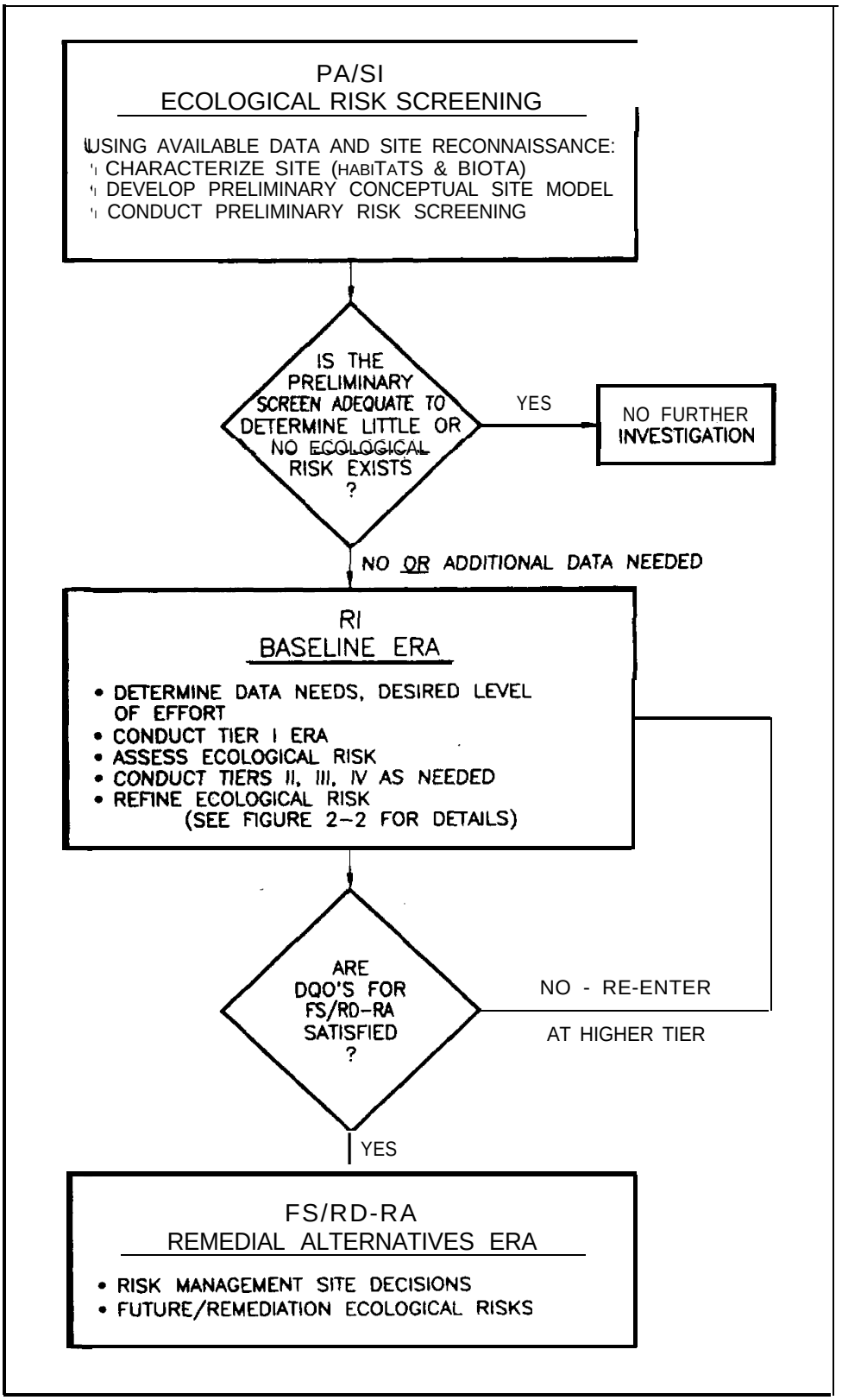

Figure 2-1. ERA flow chart

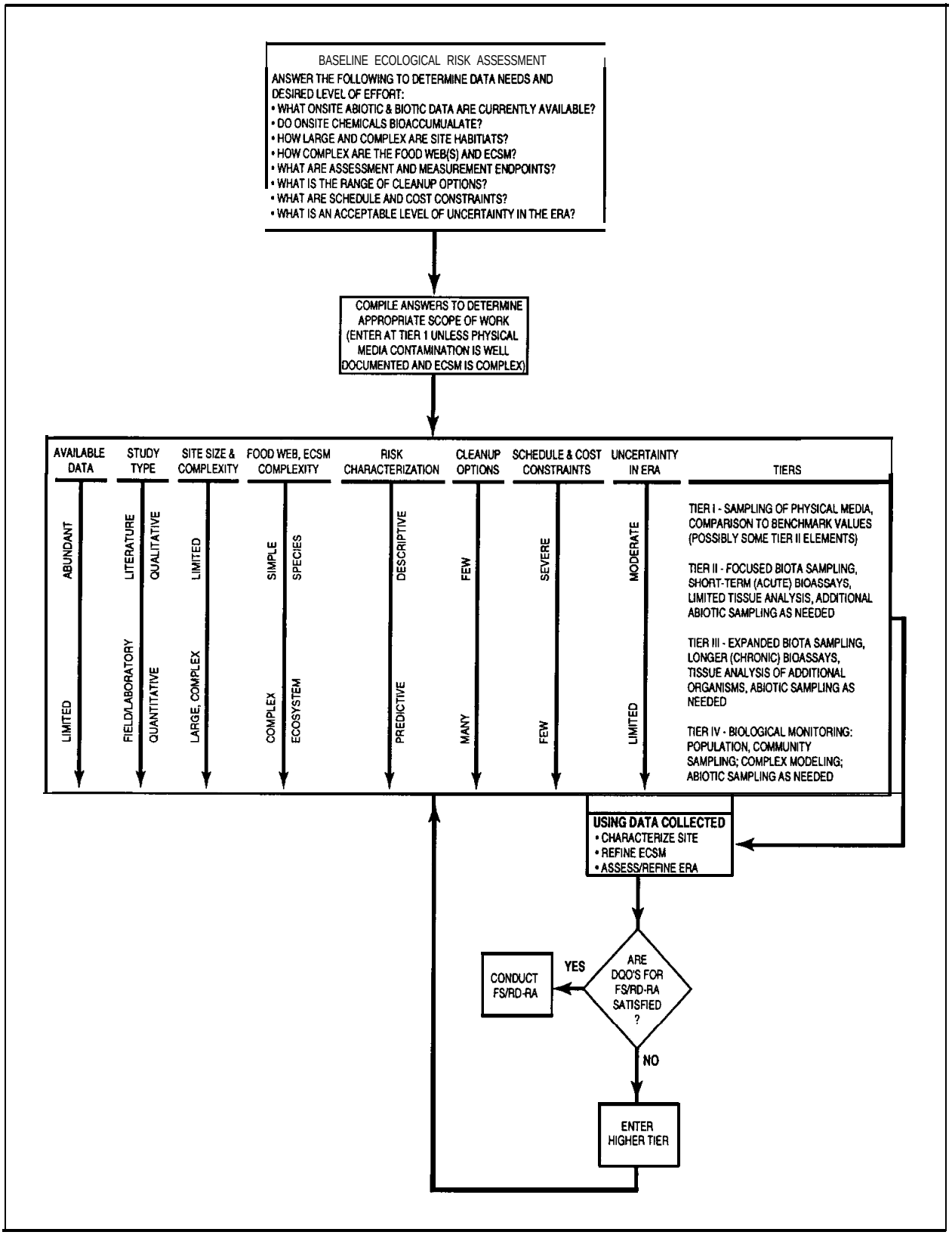

Figure 2-2. Baseline ERA flow chart

way, the trustee can be assured that potential environmental concerns are addressed and conclusion of action may be expedited (EPA 1989a). Coordination with natural resource trustee agencies such as NOAA provides for the exchange of ideas and issues to ensure the technical adequacy of the RI/FS, to ensure the protectiveness of the selected remedy for trust resources, and to provide for proper restoration and mitigation for injured resources. Coordination also allows DoD access to the trustees' specific skills, information, and experience in ERAs. This interaction may occur through a variety of informal and formal forums, including but not limited to: preliminary scoping and drafting of work plans, review of final work plans and subsequent data, technical review committees, PM/TM meetings, and public information meetings.

2.2.4 HTRW Policy and Technical Project Planning

The ERA process presented herein is consistent with DoD and EPA policy and guidance. Recent EPA (1995d) risk characterization guidance reaffirms the principles and guidance found in earlier EPA (1992g) policy, Guidance on Risk Characterization for Risk Managers and Risk Assessors. EPA's (1995a,d) risk characterization policy establishes the core values of clarity, transparency, reasonableness, and consistency in both ecological and human health risk assessments across Agency programs. Adherence to this policy is intended to:

- Ensure that risks are characterized fulIy, openly, and clearly.
- Promote full disclosure of scientific analyses, uncertainties, assumptions, science policies, and the rationale which underlie decisions as they are made throughout the risk assessment and risk management process.
- Improve the understanding of ERAs, to lead to more informed decisions, and to heighten the credibility of both the risk assessment and risk management decisions.

Risk management is an important aspect of USACE's HTRW program. To ensure the utility of the ERA in meeting risk management needs, the HTRW Technical Project Planning process laid out in EM 200-1-2 (USACE 1995b) should be followed. In accordance with this planning process, the USACE PM and/or TM provides the leadership to define a site strategy and to effectively communicate this strategy.

Risk assessment is based on a series of questions about scientific information that is relevant to the estimation of risk. Each question calls for analysis and interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem, and scientific conclusions regarding the questions presented. The HTRW planning process is used to focus on data needs and to design quality data collection options. The HTRW planning process also encourages early refinements of the data collection options as a means of identifying cost-effective options for selection. By emphasizing the process, it is expected that the ERA will be useful as a site-decision-making tool.

2.2.5 The HTRW Technical Project Planning Process

USACE recognizes the need for cost-effective and efficient site investigation/response actions. The HTRW Engineer Manual 200-1-2, *Technical Project Planning Guidance for HTRW Data Quality Design* (USACE 1995b) provides guidance on data collection programs and defines DQOs for HTRW sites. The HTRW technical project planning process is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options.

DQOs define the project's data needs, data use, number of samples desired, the associated quality assurance requirements (e.g., detection limits, blanks, split and duplicate samples, etc.), and level of confidence or acceptable data uncertainty for the requisite data. DQOs are generated at the final phase (Phase IV) of the HTRW data quality design process after the customer has selected the preferred data collection program (ER 1110-1-263, USACE 1995c). The process includes evaluation of previously collected data and assessment of need for additional data to support the study elements for the current or subsequent phases of the project. 'Ibis coordinated project planning effort is designed to satisfy the customer goals, applicable regulatory requirements, and minimum technical data requirements for performing a site-specific ERA.

Throughout the process, USACE HTRW personnel of various disciplines and responsibilities work closely together to identify data needs, develop data collection strategy, and propose data collection options. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all

phases of the project life cycle. The DQO development process is considered to be a total quality management (TQM) tool (EPA 1989e). Incorporating the HTRW data quality design and technical project planning process is key to ensuring successful planning and performance of the ERA.

Three basic questions related to the use of the HTRW technical project planning approach are:

- What decisions are the data intended to resolve? What are the primary and secondary regulatory programs that require data input? What are the customer's goals and concept of site closeout? Where is the project phase under such program(s)? What are the PDs for the project phase?

- Why does the customer (or the data user) need a specific type and quality of data? What are the study elements for the project phase? What are the minimum data requirements for the study elements? What am the data quality requirements to satisfy PDs? (For example, to eliminate sites early in the project phase based on the lack of ecological resources of concern, the study element could be an environmental survey and assessment to identify the presence or lack [unrelated to contamination] of ecological resources of concern. The data quality associated with the survey and assessment will need to be specified. Involved parties would also have to agree on the finding that ecological resources of concern [potential assessment endpoints] are absent.)

- How will data be used to defend site decisions? How will the results of the study be used to satisfy PDs? What are the data collection options and anticipated removal/remedial options, if applicable? What is the customer's preference or choice for the options? How should the selected option(s) be implemented? (If sensitive receptors are identified at a site, the customer may choose to further evaluate the impact by collecting data to support a baseline ERA. Alternatively, the customer may chose to negotiate with the regulatory agencies on various interim measures or remedial actions to mitigate the release or rehabilitate the site).

Phases I through IV (described below) of the HTRW technical project planning elements address the above questions methodically and should be incorporated or used in the entire HTRW project life cycle. Using this technical project planning process, the risk assessor will be able to define minimum information requirements for risk evaluations in support of site decisions. Further explanation of the HTRW data quality design approach as it relates to the conduct of the ERA is provided in Appendix D. The utilization of key information identified in the ERA for risk management decision-making is described in Chapter 9.

2.2.5.1 Phase I - Develop Project Strategy

This phase of the project planning process involves identifying site decision requirements and developing an approach to address these requirements. Site strategy is broadly defined in the beginning of a project at this stage. As the project progresses into subsequent phases, the strategy is refined based on an improved understanding of the site. The risk assessor is crucial to the development of appropriate site strategy in this phase and the identification of data needs/quality to support risk management decisions. In this planning phase, site conditions am reviewed qualitatively, and a preliminary ECSM is developed to help define the study elements for the current and subsequent project planning phases. In terms of project execution, key inputs required for decision-making can be more readily defined after site-specific conditions are generally understood.

2.2.5.2 Phase II - Identify Potential Data Needs to Support Decisions

This phase of the project planning process focuses on identifying data needs and minimum data quality requirements to support site decisions identified in the PDs. Data users identify potential data needs and their respective proposed quality assurance/quality control requirements based on site background, regulatory information, and the customer's goal. At this phase, the compliance specialist, remedy-design engineer, and responsibility-legal data users, who have specific data needs, present their data requirements along with the data needs identified by the risk assessor. The objective is to scope out data needs and quality requirements by ah project team members. Data requirements are documented so that the data implementors, chemists, geologists, and/or statisticians may recommend potential optimum sampling design and data collection options for selection and implementation.

At most sites it is unusual for massive, adverse, ecological effects impacting sensitive species or valued resources (assessment endpoints) to be readily observed in a field survey. Consequently, multiple data or measurement

endpoints are needed to infer or link the collected data with the assessment endpoints. The likelihood or tendency to overscope data needs at this project planning phase is high, if an iterative approach is not followed. The danger of falling into a trap of endless research studies without added benefits can readily occur if the risk assessor attempts to address all uncertainties in a single study.

Contaminants found on many CERCLA/RCRA sites are commonly localized to small areas. In these cases, perturbations on the overall structure and function of valued (societal and ecological) populations (excluding threatened and endangered species), communities, or ecosystems are often found to be negligible. Depending on the specific site conditions (or presence of protected receptors), simple screening methods and limited field studies or bioassays (e.g., Tier I or Tier II approach as described in Chapters 4 and 5, respectively), are frequently adequate for risk management decision-making.

To select the proper risk assessment approach, given time and resource constraints, it is important that the risk assessor has the proper training and experience to scope and manage the ERA. To the extent feasible, the experience and skill of expert ecologist(s) and advisory groups (BTAG/ETAG) should be leveraged when identifying the data needs for the ERA. Data needs consistent with customer's goals and concept of site closeout, time/budget, site and project strategy, PDs, and the project study element requirements are documented as part of the Phase II requirements. This information in turn is communicated to the data implementors for developing sampling strategies and data collection options under Phase III.

2.2.5.3 Phase III - Identify Data Collection Options

This phase of the technical project planning process incorporates previously identified data needs and project constraints in designing a data acquisition approach. Various sampling approaches can be used, ranging from purposive (judgmental or biased) to representative sampling methods. Data may also be obtained from single-step to multi-step abiotic (media) investigations, from single species and microcosm (multitrophic levels) laboratory toxicity tests to mesocosm, sentinel and field surveys, or to long-term (multiseasons and multiyear) modeling and monitoring studies of ecological community function and reference areas to satisfy data needs critical for the site decisions.

This phase of project planning also involves identifying the optimum sampling/data collection scheme so as to minimize mobilization, field sampling, and demobilization efforts and costs. The objective of Phase III is to identify options (preferably two or three options, out of which one is an optimum option) for presentation in Phase IV.

2.2.5.4 Phase IV - Select Data Collection Options and Assign DQOs

This is the most important phase of the project planning/ execution process, because this is where data collection options are selected. To properly execute Phase IV, the proposed options should be clearly explained and characterized. The discussion should include data uncertainties, cost/benefits, schedule, and other constraints. Based on feedback from the customer or decision-maker, the project team may have to refine the preferred option(s). Prior to the presentation of options, it is recommended that the PM or TM review the options to determine if they are consistent with site strategy and meet the requirements of the PDs.

The project team critically reviews the output from Phase I through Phase III of the project planning process to recommend an array of options. Specifically, the project team reviews the army of data collection options and reexamines the PDs, data needs (including critical samples, i.e., samples necessary for the site decision at that project execution phase) and their quality assurance requirements, budget/tie constraints, the customer's goals, and regulatory/compliance requirements. The team reexamines whether the options meet the project strategy and whether the options are cost-effective in terms of meeting minimum data requirements of the data users and the site decision-makers for the current phase. as well as subsequent phases of the project.

Because ERAs typically have limited budget and time for completion, data requested for the ERA should be action-oriented, i.e., they should assist the customer to make informed decisions. It is critical that sufficient data are collected to address uncertainties associated with the ERA. Although such uncertainties can often be addressed via long-term research projects or studies, these are generally not appropriate under RCRA and CERCLA. The purpose of an ERA is not to prove an ecological effect or accurately predict such effect, but to reasonably determine the degree to which hazardous constituents or wastes have impacted or could impact the structure. function. and dynamics of the ecosystems (i.e., biological diversity,

functional integrity, energy and nutrient dynamics). If the impact is judged to be significant, further action will be warranted.

The products of this phase of the project planning process are the Statement of Work (SOW) for USACE work acquisition (either internal or the architectural-engineering [A-E] contractor), a detailed cost estimate for the selected option, and DQOs for the data collection program. The DQOs explain the objectives of the data gathering activity, the data type/location, data collection and analytical methods, rationale for requiring certain data quantity and quality, and how the data are to be used in making site decisions. If the acquisition strategy in Phase I technical project planning was to seek assistance of an A-E contractor, the DQOs and the appropriate information from Phases I through III will also be provided to the contractor to develop the Sampling and Analysis Plan (SAP) (synonymous with Chemical Data Acquisition Plan. USACE 1995a,b), in order to meet the goals and objectives of the next executable phase of the project life cycle. Caution should be taken at this point about the integration and coordination between the human health assessment and ERA as to how they influence DQOs. RAs may require lower media-specific detection limits than human health assessments for certain COECs and vice versa. The ultimate DQOs should be the lower of either for dual purpose samples, or the appropriate concentration for specific purpose samples.

Depending on the level of expertise and familiarity of the contractor with the project, the USACE HTRW PM may elect to allow the contractor to assume some responsibilities to complete Phases II through IV, with input from USACE. In terms of technical project planning for ERAs, it is critical that the contractors are trained and understand the Corps ERA approach, the customer's objectives and site strategy, and have the required experience.

The Phase IV project planning process involves the selection and documentation of the data collection program in support of an ERA or risk analysis. Such documentation will provide a historical knowledge which justifies and guides the data review and data use.

2.2.6 Approaches to the Conduct of an ERA

The approach and level of effort for an ERA are based on DQOs developed under the HTRW technical project planning process. DQOs address data quality and quantity requirements and data use. DQOs am integral to the design and conduct of cost-effective and efficient ERAs under current and future land-use scenarios.[7] While the overall framework for the conduct of the risk assessment should remain consistent with the Framework paradigm, the risk assessor may apply a variety of approaches and classification schemes in the conduct of the ERA. Two distinct approaches are generally seen in ERAs: the criteria-based approach and the ecological effects-based approach.

A preliminary ERA screen is generally based on the criteria or chemical concentration-based approach. Chemical criteria, such as state and Federal ambient water quality criteria (AWQC) or naturally occurring background concentrations, are routinely screened against in the initial investigation stage of an ERA. Ecotoxicological risk-based screening concentrations (RBCs), similar to human health RBCs, are being developed in some EPA regions. These chemical screening concentrations represent conservative values that are designed to be protective of specific ecosystems (aquatic, terrestrial, wetland) and can serve as a technical basis for the development of site-specific cleanup objectives. Numeric screening concentrations, however, are not available for a great many chemical contaminants.

The ecological effects-based approach is more commonly applied in the baseline ERA. This approach is based on the detailed evaluation of site-specific conditions using toxicity tests or actual biological measurements. This approach is commonly applied to aquatic ecosystems, where standardized American Society for Testing and

[7] For example, if the intended use of the site after site closeout is a park/recreation area, the data to be collected to support the ERA will be quite different from the future land use of an industrial park. The former may involve identifying the potential ecological receptors of concern (based on a reference park/recreational area), availability of food sources, and assessing the potential effects of the potential COECs, under the no-further-action scenario. The data needs and DQOs for the latter land use may only include collecting data to ensure that the current site condition and its conversion to an industrial park will not impact potential ecological receptors in the vicinity of the site, including those in surface water bodies. EPA's land use guidance, *Land Use in CERCLA Remedy Selection Process* (EPA 1995e) and other land use information should be reviewed as part of the HTRW technical planning process.

Materials (ASTM) test methods may be used. This causal evidence approach allows for the identification of biological or ecological impacts without specific accountability for the chemical causative factors and is not constrained by the limitations of chemical analytical techniques. Chemical concentration data are used primarily to establish general accordance. As proof of causality is not a requirement for the ERA, the evaluation of causal evidence is used co augment the risk assessment. Criteria for evaluating causal associations have been suggested by Hill (1965) and are provided in EPA's (1992a) *Framework.*

Both of these approaches are part of the overall strategy of the Framework approach for establishing site-specific remediation objectives (see Section 2.3). The following chapters are directed more toward the former approach in their presentation of the quotient methodology and discussion of risk-based screening concentrations. The toxicity test approach is described in much greater detail in two recent documents: *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994) and *Methodology for Aquatic Ecological Risk Assessment* (WERF 1994).

ERAs also entail the use of various classification schemes such as: qualitative versus quantitative, predictive versus retrospective, empirical versus theoretical, and top-down versus bottom-up methods. These schemes have been described in publications by Parkhurst et al. (1990), Norton et al. (1988). and Pastorok and Sampson (1990) 'and in Environment Canada's (1994) *Framework for ERAs.* Use of a particular classification scheme rests on site-specific objectives and, to a great degree, the knowledge and experience of the risk assessor.

2.2.7 Establishing the Level of Effort

The preliminary level of effort and nature of the ERA are directly related to the PDs that need to be addressed. Boundaries need to be set early in the scoping process, since the amount of information that could be. incorporated into an ERA is potentially limitless. Although often predetermined to a large extent by schedule and budget constraints, these boundaries should be tied to the objectives of the preliminary assessment and the site-specific nature of the potential risk.

Before initiating the ERA, project planning is generally conducted to help set priorities and establish budget constraints. Early project planning establishes the focus and complexity of the ERA. Project planning includes a review of the available background material and discussions to define the scope and critical aspects of the ERA. Spatial boundaries such as the size of the site, extent of contamination, potential threats to onsite and nearby ecosystems, and important ecosystem components (e.g., fisheries) greatly determine the potential scope and design of the ERA. Any remediation or restoration plans for the site should be considered in the planning stage. Data deficiencies should also be recognized at this stage to the extent possible. Recognizing these planning elements and articulating specific objectives early in the planning stage will drive the design and focus of the subsequent ERA efforts. The methodology for conducting an ERA, as described in this manual, is based on a four-tiered approach. The four-tiered approach is introduced in Section 2.4 and presented in detail in Chapters 4 through 8.

2.3 Introduction to the ERA Process

This ERA process presented herein is based on EPA's *Framework* and its risk paradigm for ecological assessments. The framework consists of three major phases or parts: (1) problem formulation, (2) analysis, and (3) risk characterization. Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the risk assessment. Its end product is a conceptual model that identifies the environmental values to be protected (assessment endpoints), the data needed (measurement endpoints), and the analysis to be used. The analysis phase develops profiles of environmental exposure and ecological effects of the COECs on the receptors of concern. The exposure profile characterizes the ecosystem, in which the COECs may occur, as well as the biota that may be exposed. The exposure profile also describes the magnitude and spatial and temporal patterns of exposure. The ecological effects profile summarizes data (or in some cases, bioassessment results) on the effects of the COECs on the receptors of concern and relates them to the assessment and measurement endpoints. Risk characterization integrates the exposure and effects profiles. Risks can be estimated using a variety of techniques including comparing individual exposure and effects values, comparing the distribution of exposure and effects, or using simulation models. Risk can be expressed as a qualitative or quantitative estimate. depending on the available data.

Most ERAs include an initial risk screening assessment to provide an initial delineation of the problem and to help structure the baseline ERA should one be needed. The screening ERA is a streamlined version of the complete *Framework* process and is intended to allow a rapid determination by the risk assessor and risk manager if the site poses no or negligible risk. The basis of the screening level assessment is the ecological site characterization and

the comparison of site abiotic media concentrations with existing environmental criteria and guideline values (i.e., ARARs), such as Federal and state[8] AWQC: marine sediment effects levels (Long et al. 1995); freshwater sediment effects levels (Persaud, Jaugumagi, and Hayton 1992); or other readily available screening-level ecotoxicity values. The basis for applying the existing environmental criteria and guidelines draws on factors introduced later and presumes an understanding of the risk assessment methodology.

Environmental criteria such as Long et al.'s (1995) sediment criteria, EPA's (1993b) proposed sediment criteria, or EPA AWQC are not the same as remediation levels discussed in Chapter 8. In general, environmental screening criteria should be highly conservative and should not necessarily be applied as cleanup objectives at a site. The sediment criteria and AWQC may be used as a screening tool prior to the performance of an RI or RFI. Remedial levels are developed later from the site-specific baseline ERA and are tailored to site ecology as well as management objectives. The biological/ecological basis for each screening criterion should be carefully considered if used for more than screening, since it is entirely possible that such criteria could be overprotective or underprotective of the potentially exposed receptors, depending on site-specific biological, physical, and chemical characteristics.

A screening ERA may be performed for a PA/SI (RFA), or as the initial step in the RI (RFI) baseline ERA. In addition to environmental criteria, other factors that should be considered in the screening ERA include habitat suitability (e.g., absence of suitable habitat because location is an industrial area) and exposure pathways (e.g., absence of complete exposure pathways to ecological receptors). If the initial risk screen suggests the site cannot be eliminated based on environmental criteria or suitable habitat and exposure pathway considerations, project planning may occur to review the screening results and define the scope and critical aspects of performing a baseline ERA. Spatial boundaries such as the size of the impacted areas or potential threats to important ecosystem components (e.g., threatened and endangered species and their habitat) greatly determine the potential scope and design of the baseline ERA. Data deficiencies may be determined early on as part of the risk screen. Recognizing these planning elements and articulating specific objectives early in the risk screening stage will determine the need and drive the design and focus of the baseline ERA. The decision to continue beyond the preliminary ecological risk screen does not indicate that risk is unacceptable or that risk reduction is necessary, rather it indicates that a more focused evaluation and characterization of the risk and accompanying uncertainty is needed.

The baseline ERA is a process that combines data from biotic and abiotic media along with exposure and toxicity information to provide a determination of environmental risk. The methodology presented in this chapter for performing the baseline ERA has largely been developed by EPA for activities undertaken under CERCLA. This methodology is appropriate for ERAs performed as part of CERCLA RIs or RCRA RFIs. as well as many other situations. The two primary guidance documents that form the basis for the discussion on ERA methodology include:

- *Risk Assessment Guidance for Superfund - Volume II: Environmental Evaluation Manual (RAGS II).* Interim Final. (EPA 1989a).

- *Framework for Ecological Risk Assessment (Framework).* Risk Assessment Forum. (EPA 1992a).

Supporting Federal and state guidance documents, methods documents, and information sources are provided in Appendix B.

The baseline ERA provides an objective, technical evaluation of the potential ecological impacts posed by a site. The baseline ERA should be clear about the approaches, assumptions, limitations, and uncertainties in the evaluation to enable the risk assessor and manager to interpret the results and conclusions appropriately. The baseline ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

While the methodology for conducting the ERA is presented in detail in the following chapters, this manual is not intended to be a step-by-step instruction manual. Rather, it is intended to be a guide for scoping and critically evaluating the screening and baseline ERAs. Adequate guidance is provided in other resources for performing and preparing an ERA, and is referred to throughout the remainder of the manual. This and the following chapters discuss the important components of the screening and baseline ERAs, highlighting where up-front planning and professional judgment are needed. The

[8] Both state and Federal AWQC should be reviewed as state AWQC can be more stringent than the Federal criteria.

goal in providing the following detailed description of the baseline ERA process is to enable a risk manager to critically appraise the scope, conduct, and quality of an ERA for his or her site.

2.4 Introduction to the Four-Tiered Approach

A four-tiered approach is incorporated in the conduct of a baseline ERA and the evaluation of potential adverse effects on ecological receptors. The four tiers are:

- Tier I - Preliminary Ecological Risk Assessment: The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical-concentration based approach.

- Tier II - Focused Biological Evaluation and Sampling: The Tier II ERA is recommended where there is a need to reduce uncertainty or verify Tier I findings by using a biological effects-based, sampling approach.

- Tier III - Expanded Sampling Program: The Tier III ERA is recommended where longer term or more extensive biological or chemical sampling programs are needed to resolve issues presented by larger sites having complex ecosystems.

- Tier IV - Monitoring Program: The Tier IV ERA is reserved for the largest and most complex sites and is only appropriate where multiple year, biological monitoring or sampling programs are needed, and an ERA with the highest degree of certainty is required.

The tiered approach to the baseline ERA is composed of sequentially more sophisticated and complex evaluations. Therefore, scoping of the ERA for different tiers will require various data needs to be satisfied. Sequential evaluation, feedback, and flexibility allow for sound scientific judgments and efficient use of resources by minimizing unnecessary data collection, focusing major efforts, and optimizing benefits. Each tier has a similar three-part framework and builds upon knowledge. data, information, and decisions from the preceding tier, with each becoming progressively more focused. Although each tier is, in essence, a stand-alone evaluation, consistency and continuity are needed to keep the focus on assessment endpoints intact as the baseline ERA proceeds to higher tiers.

Within each tier, the baseline ERA, like the screening ERA, consists of the three major parts described in EPA's Framework:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

The tiered approach to the baseline ERA is an iterative process, with each subsequent tier including the same three parts, but building on information provided in the previous tier. Within each tier, new biological, toxicological, and abiotic chemical data are collected or evaluated. in order to revise and focus the ERA effort (see Figure 2-2). Also, within each higher tier, the data collection effort generally shifts from direct chemical analyses of abiotic media to short-term biotic sampling to longer term biotic sampling. The tiered approach is designed to address a series of questions regarding ecological conditions and effects at a site. Decisions are made in each tier as whether to proceed to the next tier and what specific sampling analyses should be conducted, based on the adequacy of data collected up to that point. While proceeding to the next tier may entail an expansion of time and effort, use of the iterative tiered approach provides a way to focus the ERA on specific decisions and DQOs throughout the process. The tiered approach offers an opportunity for decision-making at a variety of steps and thereby eliminates unnecessary testing and focuses resources on the important problems.

Tiering of a site-specific ERA is intended to provide a flexible, cost-effective management mechanism for the site investigation. While the baseline ERA process follows the simplified Framework structure, the actual level of effort within and between tiers may be both nonsequential and iterative. The order of actions taken depends on site status, RI/FS or RFI/CMS stage, amount and types of site information available, the necessity of multiple sampling events, and other factors. While the tiered approach is intended to maximize efficiency of data collection, there are cases where the tiered approach may require multiple field programs or time delays. In some cases, logistics and cost considerations outweigh the benefits of tiered testing. The scope of the effort and cost/benefit of applying the tiered approach are determined

through project planning, DQO evaluation, and through risk management decisions based in part on the results of the screening ERA.

Overall, the tiered approach is designed to ensure that all procedures to be performed are appropriate, necessary, and sufficient to characterize the nature and extent of effects to biota under the current and future land (or resource) use scenarios. To evaluate the relationship between contamination and ecological effects, the tiered approach requires iterative reevaluation of strategy objectives and data needs throughout the process, based upon the integration of three types of information:

- Chemical: Chemical analyses of appropriate media to establish the presence, concentrations, and variabilities of specific toxic compounds.
- Ecological: Ecological information to document potentially exposed ecosystems and populations (or threatened and endangered individuals): to characterize the condition of existing communities; and to observe whether any obvious adverse effects have occurred or are occurring.
- Toxicological: Toxicological and ecotoxicological information or testing to establish the link between adverse ecological effects and known contamination.

Without these three types of data, other potential causes of the observed effects on ecosystems unrelated to the presence of contamination, such as natural variability and human-imposed habitat alterations, cannot be eliminated. Use of the tiered approach is intended to maximize the efficiency of data collection in each of these three areas, using the information obtained at each tier to focus on the problem, and optimize the design of the next tier, if needed.

The four tiers and their interrelationship are shown on the flow charts in Figures 2-1 and 2-2. Figure 2-1 shows the overall relationship of the baseline ERA to the screening ERA and the Remedial Alternatives ERA (FS/RD-RA). Figure 2-2 shows the interrelationship of the four tiers within the baseline ERA. As shown in Figure 2-2, the number of tiers likely to be included in the baseline ERA depends on the PA/SI screening ERA results, specific project planning objectives and determination of data needs (see USACE's [1995b] HTRW Technical Project Planning document), and potential constraints such as schedule and cost, or cleanup options. Whether or not to proceed from the Tier I ERA to a focused biological field sampling program (Tier II), or an expanded biological sampling program (Tier III), or a multiple-year sampling program (Tier IV) will depend on how decision data needs are satisfied during the Tier I effort.